

Pfizer Independent Research Grant Request for Proposals

Competitive Grant Program – Pfizer Internal Review Process

Pharmacokinetics-pharmacodynamics (PK-PD) of aztreonam-avibactam (ATM-AVI) in Special Populations



Overview

This RFP invites research submissions focused on studying the PK-PD of ATM-AVI in special populations.

In scope are adult patients with suspected or documented CRE-MBL infections who are critically ill, including those undergoing ECMO or CRRT, as well as those experiencing septic shock, or with CRF, ESRD, or morbid obesity.



Geographic Scope

Austria, Denmark, Finland, Germany, Italy, Netherlands, Norway, Romania, Spain, Sweden, and UK.

*Limited to marketing authorization and supply distribution



Project Types and Area of Interest

Potential applicants are requested to submit research proposals to study PK-PD of ATM-AVI for CRE-MBL in special population.

- PK-PD and target attainment in patients with CRF, ESRD including on different modalities of CRRT.
- PK-PD and target attainment in patients with septic shock, including those on ECMO.
- PK-PD and target attainment in morbidly obese patients.
- PK-PD and tissue penetration study to characterize concentrations of ATM-AVI in ELF in critically ill patients and concentration in bone, joint spaces, or meninges in patients with HAP/VAP, osteomyelitis, or central nervous system infection.



Key Milestones:



Funding Range and Project Length

Individual projects requesting up to \$60,000 USD will be considered. The total budget for this RFP is \$300,000 USD.

Maximum project length is 12 months.

I. Eligibility

Geographic Scope:

Austria, Denmark, Finland, Germany, Italy, Netherlands, Norway, Romania, Spain, Sweden, and UK.

*Note: For logistical reasons, proposals will be considered only if ATM-AVI is commercially available in the country at the time of the RFP release. The drug supply is limited to countries where ATM-AVI has regulatory marketing authorization and existing supply chains.

Applicant Eligibility Criteria:

- The institution and Principal Investigator (PI) must be based in one of the eligible countries noted above.
- Only organizations are eligible to receive grants, not individuals or medical practice groups (i.e., an independent group of physicians not affiliated with a hospital, academic institution, or professional society).
- If the project involves multiple departments within an institution and/or between different institutions / organizations / associations, all institutions must have a relevant role and the requesting organization must have a key role in the project.
- The PI must have a medical or postdoctoral degree (MD, PhD, or equivalent), an advanced nursing degree (BSN with a MS/PhD), or a degree in Pharmacy, Physiotherapy, or Social Work.
- The applicant must be the PI or an authorized designee of such individual (e.g., PI's research coordinator).
- The PI must be an employee or contractor of the requesting organization.
- Requesting organization must be legally able to receive award funding directly from Pfizer Inc. We strongly recommend that applicants confirm this with their organization or institution prior to submitting an application. Grants awarded to organizations that are subsequently found to be unable to accept funding directly from Pfizer Inc. may be subject to rescission.

II. Requirements

Primary Area of Interest:

Infectious Disease - Bacterial - RES

General Area of Interest for this RFP:

The intent of this Request for Proposals (RFP) is to invite research submissions focused on studying the pharmacokinetics and pharmacodynamics (PK-PD) of Aztreonam-Avibactam (ATM-AVI) in special populations.

- PK-PD and target attainment in patients with chronic renal failure (CRF), end-stage renal disease (ESRD) including those on different modalities of continuous renal replacement therapy (CRRT)
- PK-PD and target attainment in patients with septic shock, including those on extracorporeal membrane oxygenation (ECMO)
- PK-PD and target attainment in morbidly obese patients
- PK-PD and tissue penetration study to characterize concentrations of ATM-AVI in epithelial lining fluid (ELF) in critically ill patients and concentration in bone, joint spaces, or meninges in patients with hospital-acquired pneumonia or ventilator-associated pneumonia (HAP/VAP), osteomyelitis, or central nervous system infection.

Expected Approximate Monetary Range of Grant Applications:

IMPORTANT: Grants will be distributed following a fully executed agreement and submission of Final Protocol, Documentation of IRB/IEC Approval, Regulatory Approval (if applicable), Exemption or Waiver.

Individual projects requesting up to \$60,000 USD will be considered. The estimated total available budget related to this RFP is \$300,000 USD. A total of 5 projects will be awarded.

Award amounts include direct costs, institutional overhead costs (capped at 28% per Pfizer policy), and indirect costs.

Note: grant requests for drug/compound are not in scope of this RFP. Pfizer will not supply formulated study drug nor pure substance.

Key Dates:



IMPORTANT: Be advised applications submitted after the due date will not be reviewed.

*Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5)

How to Submit:

IMPORTANT: Please read this section carefully since applications submitted not following these instructions will not be accepted and will be cancelled.

Please go to www.cybergrants.com/pfizer/Research and sign in.

Note: there are individual portals for each grant application type. Please be sure to use the URL above.

First-time users should click "Create your password".

Click the "Start A New Research Grant Application" button.

Requirements for submission:

Complete all required sections of the online application

IMPORTANT: Upload proposal (see Appendix) in the Proposal/Protocol field.

In the application:

For the question "Competitive Grant?" select "Yes"

Select the following Primary Area of Interest: **Infectious Disease - Bacterial - RES**

Select the following Competitive Grant Program Name: **2025 I&I G PK-PD of ATM-AVI in Special Populations RES**

Questions:

If you encounter any technical difficulties with the website, please click [here](#) or the “Technical Questions” link at the bottom of the page in Cybergrants.

Please click [here](#) to view “Frequently Asked Questions” regarding the Competitive Grant Program.

If you have questions regarding this RFP, please direct them in writing to the Grant Officer, **Talita Honorato-Rzeszewicz** (Talita.Honorato-Rzeszewicz@pfizer.com), with the subject line “**PK-PD (Pharmacokinetics-Pharmacodynamics) of Aztreonam-Avibactam in Special Populations 2025**”.

Review and Approval Process:

Grant requests received in response to a general RFP are reviewed by Pfizer to make final grant decisions.

Mechanism by which Applicants will be Notified:

All applicants will be notified via email by the dates noted above.

Applicants may be asked for additional clarification during the review period.

Grant Agreements:

If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer. Please click [here](#) to view the core terms of the agreement.

Under Pfizer's competitive grant program, modifications to grant agreements will not be reviewed unless a genuine conflict exists as between applicable law and the terms of the relevant grant agreement. Applicant is encouraged to share the core terms with counsel for approval prior to submitting an application.

Except where prohibited by applicable law and, in any case, subject to review by Pfizer Legal, payment of grant funding may only be paid to the grantee organization.

This RFP is supported by Pfizer Inc. and, if approved, payment will be sent from the United States.

References:

Das S, Riccobene T, Carrothers TJ, et al. Dose selection for aztreonam-avibactam, including adjustments for renal impairment, for Phase IIa and Phase III evaluation. *Eur J Clin Pharmacol.* 2024;80(4):529-543. doi:10.1007/s00228-023-03609-x. [Link to abstract](#)

About Pfizer Grants:

Pfizer supports the global healthcare community's independent initiatives (e.g., research, quality improvement or education) to improve patient outcomes in areas of unmet medical need that are aligned with Pfizer's medical and/or scientific strategies.

Pfizer's competitive grant program involves a publicly posted general Request for Proposal (RFP) that provides detail regarding a general area of interest, sets timelines for review and approval, and uses an internal Pfizer review process to make final grant decisions. Organizations are invited to submit an application addressing the research gaps as outlined in the specific RFP.

For all Investigator Sponsored Research (ISRs) and general research grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, sponsorship, and conduct of the independent initiative supported by the grant, including compliance with any regulatory requirements. Pfizer must not be involved in any aspect of study protocol or project development, nor the conduct or monitoring of the research program. An ISR grant request cannot be submitted for a study that has already commenced and was not originally supported by Pfizer.

Appendix

IMPORTANT: RFP Submission Requirements

Applications will be accepted via the online portal listed in the How to Submit section. Project Proposals/Protocols should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a **15-page limit**, exclusive of references. When uploading your Full Proposal please ensure it addresses the following sections:

Goals and Objectives

Provide the main goal of the study and the study population (if applicable). Provide a detailed definition that is directly linked to the primary objective.

Assessment of Need for the Project

This should reflect your study rationale. Provide a brief description of the medical/scientific question and the rationale of how this trial or study addresses the question.

Target Audience

Describe the primary audience(s) targeted for this project. For Investigator Sponsored Clinical Trials, please specify the age, gender and other demographic information for trial population.

Also indicate whom you believe will directly benefit from the project outcomes. Describe the overall population size as well as the size of your sample population.

Project Design and Methods

Describe concisely the research design and methods for achieving the stated goals. For a clinical interventional study, include inclusion/exclusion criteria, treatment plan and statistical plan.

Innovation

Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects. Describe how this project builds upon existing work, pilot projects, or ongoing projects developed either by your institution or other institutions related to this project.

Evaluation and Outcomes

Specify type and frequency of safety, efficacy, and/or outcome measures. Also indicate the method(s) used to assess measures.

Provide a publication plan describing intended submission of abstracts to (a) congress(es) or intended submission of (a) publication(s) to peer-reviewed journals.

Anticipated Project Timeline

Provide an anticipated timeline for your project including project start/end dates.

An ISR grant request cannot be submitted for a study that has already commenced and was not originally supported by Pfizer.

Additional Information

If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize here.

Early-career applicants: Letter(s) of support from mentor(s) and collaborators describing how the award will advance the applicant's career.

Organization Detail

This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used [laboratory, animal, clinical and "other"]. If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project.

Budget Detail

The budget amount requested must be in U.S. dollars (USD).

While estimating your budget please keep the following items in mind:

General organizational running costs such as legal fees, insurance, heating, and lighting etc. should be included in an Institutional Overhead (if required). These costs are not specific to a grant request and therefore, should not appear as line items in budgets. However, costs that are specific to the study (e.g., some countries require insurance to be taken out on a per-study basis for clinical research) would be acceptable to be included as line items.

The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.

Pfizer does not provide funding for capital purchases (infrastructure expenses such as equipment, purchases of software or software licenses, technology or bricks and mortar). Equipment hire/leasing is acceptable and may be included in project budget.

It should be noted that grants awarded through GMGP cannot be used to purchase Pfizer therapeutic agents (prescription or non-prescription).

Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects. Please [click here](#) for details.

Required Documents

Project Plan or Proposal

Initial Study Protocol

Organizations must obtain approval from an Institutional Review Board (IRB) for their proposal to be eligible to receive the grant award. It is not mandatory to have IRB approval at the time of proposal submission. However, organizations are anticipated to secure an IRB evaluation subsequent to the award notification and must ensure that the approval is in place prior to 22 December 2025.